STERILE WATER - water injection
Taro Pharmaceuticals U.S.A., Inc.

Rx Only
Plastic Ampule

DESCRIPTION

This preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection.
Sterile Water for Injection, USP is a sterile, nonpyrogenic preparation of water for injection, which contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single-dose containers to dilute or dissolve drugs for injection. The blow-fill-sealed twist-off top, plastic ampule is molded from a specially formulated polypropylene. For I.V. injection, add sufficient amount to a solute to make an approximately isotonic solution.
Water for Injection, USP is chemically designated H_2O. The pH is 5.0 to 7.0.

CLINICAL PHARMACOLOGY

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production). Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.
The small volume of fluid provided by Sterile Water for Injection, USP when used only as a pharmaceutic aid for diluting or dissolving drugs for parenteral injection, is unlikely to exert a significant effect on fluid balance except possibly in newborns or very small infants.

INDICATIONS AND USAGE

This preparation is indicated only for diluting or dissolving drugs intended for parenteral injection, according to instructions of the manufacturer of the drug to be administered.

CONTRAINDICATIONS

Sterile Water for Injection, USP must be made approximately isotonic prior to use.

WARNINGS

Intravenous administration of Sterile Water for Injection without a solute may result in hemolysis.
Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle. Consult with pharmacist, if available.
The plastic ampule is molded from a specially formulated polypropylene.
When diluting or dissolving drugs, mix thoroughly and use promptly.
Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute.

PRECAUTIONS

Do not use unless the solution is clear and seal intact. Do not reuse single-dose containers, discard unused portion.
Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection.
Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

Pregnancy Category C

Animal reproduction studies have not been conducted with Sterile Water for Injection, USP. It is also not known whether Sterile Water for Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile Water for Injection, USP with additives should be given to a pregnant woman only if clearly needed.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with solutions in polypropylene ampules have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Drug Interactions

Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle. Consult with pharmacist, if available.
When diluting or dissolving drugs, mix thoroughly and use promptly.
Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute.
Do not use unless the solution is clear and seal intact. Do not reuse single-dose containers. Discard unused portion

ADVERSE REACTIONS

Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, evaluate the patient, institute appropriate countermeasures, and if possible, retrieve and save the remainder of the unused vehicle for examination.

OVERDOSAGE

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of fluid overload except possibly in newborn or very small infants.

DOSAGE AND ADMINISTRATION

The volume of the preparation to be used for diluting or dissolving any drug for injection, is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer of the drug and be administered.

Use aseptic technique for entry and withdrawal from container.

This parenteral should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See **PRECAUTIONS**.

HOW SUPPLIED

NDC #	Volume
51672-3018-5	single-dose 5 mL Ampule
51672-3018-3	single-dose 10 mL Ampule

Packaged in a polypropylene ampule. Ampules are packaged 20 per tray.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

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